

PATENT

JC997 U.S. PTO
09/901836



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Valerio et al.

Serial No.: To be assigned

Filed: July 10, 2001

For: METHOD AND MEANS FOR
TARGETED GENE DELIVERY

Examiner: To be assigned

Group Art Unit: To be assigned

Attorney Docket No.: 3837.1US

NOTICE OF EXPRESS MAILING

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Date of Deposit with USPS: July 10, 2001

Person making Deposit: Jared Turner

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents are enclosed pursuant to 37 C.F.R. § 1.98(a).

In accordance with 37 C.F.R. § 1.97(g) and (h), filing of this Information Disclosure Statement is not to be construed as a representation that a search has been made or an admission that the information cited herein is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b). Further, no representation is made by Applicants herein that no other possible material information as defined in 37 C.F.R. § 1.56(b) exists.

U.S. Patent Documents

| <u>Document No.</u> | <u>Date</u> | <u>Country</u> |
|---------------------|-------------|---------------------|
| #6,033,908 | 3/7/00 | Bout <i>et al.</i> |
| #6,040,174 | 3/21/00 | Imler <i>et al.</i> |

Foreign Patent Documents

| | | |
|-------------|----------|--------|
| #FR2649119 | 1/4/91 | France |
| #EP0496074 | 7/29/92 | Europe |
| #WO/9222332 | 12/23/92 | WO |
| #WO/9309221 | 5/13/93 | WO |
| #WO/9416734 | 8/4/94 | WO |
| #WO/9412626 | 6/9/94 | WO |
| #WO/9526412 | 10/5/95 | WO |
| #WO/9700326 | 1/3/97 | PCT |

Other Documents

- #Boado, R.J. (1995) Adv. Drug Deliv. Rev., 15:73-107.
- #Curiel *et al.* (1994) Virology, 198:577-585.
- #Etienne-Julian *et al.* (1992) J. Gen Virol., (1992) 73: 3251-3255.
101. #Friedmann, T. "Overcoming the obstacles to gene therapy." Sci. Am. June 1997 pp. 96-101.
- #Marin *et al.* (1994) Gene Therapy, 1(2):s15.
- #Nilson *et al.* (1994) Gene Therapy, 1(2):s17
- #Orkin, *et al.* "Report and recommendations of the panel to assess the NIH investment in research on gene therapy," 12/95.
- #Roux *et al.* (1989) Proc. Natl. Acad. Sci., 86:9079-9083.
- #Russell *et al.* (1993) Nucleic Acids Research, 21(5):1081-1085.
- #Truong *et al.* (1993) Proc. Intern. Symp. Control. Release Bioact. Mater., 20: 474-475.

#Verma *et al.* "Gene therapy - promises, problems and prospects. (9/97) Nature 389:239-242.

#Zatloukal *et al.* (1993) J. Cell Biochem. 17(d):129.

#Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior application:

Serial No.: 09/000,133

Filed: February 24, 1998

For: METHOD AND MEANS FOR TARGETED GENE DELIVERY which application is being relied upon for an earlier filing date under 35 U.S.C. § 120.

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56 & 1.175, applicant hereby identifies the following listed copending applications naming the same inventors:

Serial No.: 08/820,479

Filed: 3/18/1997

For: METHODS AND COMPOSITIONS FOR GENETICALLY MODIFYING PRIMATE BONE MARROW CELLS

Serial No.: 09/298,745

Filed: 4/23/1999

For: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO BE USED IN GENE THERAPY

Serial No.: 09/326,032

Filed: 6/4/1999

For: GENETIC MODIFICATION OF PRIMATE HEMOPOIETIC REPOPULATING STEM CELLS

Serial No.: 09/333,820

Filed: 6/15/1999

For: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO BE USED IN GENE THERAPY

Serial No.: 09/381,716

Filed: 1/4/2000

For: METHODS AND COMPOSITIONS FOR GENETICALLY MODIFYING PRIMATE BONE MARROW CELLS

Serial No.: 09/502,624

Filed: 2/11/2000

For: VECTORS AND METHODS FOR PROVIDING CELLS WITH ADDITIONAL NUCLEIC ACID MATERIAL INTEGRATED IN THE GENOME OF SAID CELLS

Serial No.: 09/506,548

Filed: 2/16/2000

For: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO
BE USED IN GENE THERAPY

Serial No.: 09/599,488

Filed: 6/23/2000

For: ADENO-ASSOCIATED VIRUS AND ADENOVIRUS CHIMERIC
RECOMBINANT VIRUSES USEFUL FOR THE INTEGRATION OF FOREIGN
GENETIC INFORMATION INTO CHROMOSOMAL DNA OF TARGET CELLS

Applicants offer to supply any explanation or discussion of the documents which the
Examiner feels is necessary or desirable and which is requested.

This Information Disclosure Statement is filed within three (3) months of the filing date
of the above-identified application, and no certification pursuant to 37 C.F.R. § 1.97(c) or a fee
pursuant to 37 C.F.R. 1.17(p) is required.

Respectfully submitted,



Allen C. Turner

Registration No. 33,041

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Telephone: (801) 532-1922

Date: July 10, 2001

ACT/le/bv

Enclosures: Form PTO-1449

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| Form PTO-1449 INFORMATION DISCLOSURE CITATION IN AN APPLICATION <i>(Use several sheets if necessary)</i> | Docket Number (Optional) 3837.1US | Application Number To be assigned |
| | Applicant Valerio et al. | |
| | Filing Date July 10, 2001 | Group Art Unit To be assigned |

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09/30/00


U.S. PATENT DOCUMENTS

| EXAMINER INITIAL | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
|---------------------|--------------------|---------|---------------------|-------|----------|-------------------------------|
| | #6,033,908 | 3/7/00 | Bout <i>et al.</i> | | | |
| | #6,040,174 | 3/21/00 | Imler <i>et al.</i> | | | |
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FOREIGN PATENT DOCUMENTS

| | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | Translation | |
|--|-----------------|----------|---------|-------|----------|-------------|----|
| | | | | | | YES | NO |
| | #FR2649119 | 1/4/91 | France | | | | |
| | #EPO496074 | 7/29/92 | Europe | | | | |
| | #WO/9222332 | 12/23/92 | WO | | | | |
| | #WO/9309221 | 5/13/93 | WO | | | | |
| | #WO/9416734 | 8/4/94 | WO | | | | |
| | #WO/9412626 | 6/9/94 | WO | | | | |
| | #WO/9526412 | 10/5/95 | WO | | | | |
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OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

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| | #Boado, R.J. (1995) <u>Adv. Drug Deliv. Rev.</u> , 15:73-107. |
| | #Curiel <i>et al.</i> (1994) <u>Virology</u> , 198:577-585. |
| | #Etienne-Julian <i>et al.</i> (1992) <u>J. Gen Virol.</u> , (1992) 73: 3251-3255. |
| | #Friedmann, T. "Overcoming the obstacles to gene therapy." <u>Sci. Am.</u> June 1997 pp. 96-101. |
| | #Marin <i>et al.</i> (1994) <u>Gene Therapy</u> , 1(2):s15. |

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| EXAMINER | DATE CONSIDERED |
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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

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Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

#Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior application:

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| | Filing Date July 10, 2001 | Group Art Unit To be assigned |

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OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages, Etc.)

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| | | #Nilson <i>et al.</i> (1994) <u>Gene Therapy</u> , <u>1(2)</u> :s17 |
| | | #Orkin, <i>et al.</i> "Report and recommendations of the panel to assess the NIH investment in research on gene therapy." 12/95. |
| | | #Roux <i>et al.</i> (1989) <u>Proc. Natl. Acad. Sci.</u> , <u>86</u> :9079-9083. |
| | | #Russell <i>et al.</i> (1993) <u>Nucleic Acids Research</u> , <u>21(5)</u> :1081-1085. |
| | | #Truong <i>et al.</i> (1993) <u>Proc. Intern. Symp. Control. Release Bioact. Mater.</u> , <u>20</u> : 474-475. |
| | | #Verma <i>et al.</i> "Gene therapy - promises, problems and prospects. (9/97) <u>Nature</u> 389:239-242. |
| | | #Zatloukal <i>et al.</i> (1993) <u>J. Cell Biochem.</u> , <u>17(d)</u> :129. |

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